

Competent Regional Authority. Dirección de Regulación, Planificación y Recursos Sanitarios. Departamento de Salud. Generalitat de Catalunya

CERTIFICATE NUMBER :NCF-II/1929/001/CAT

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Spain confirms the following:

The manufacturer:**MENADIONA S.L.**

Site address:**POL. INDUSTRIAL MAS PUIGVERT S/N, PALAFOLLS, Barcelona, 08389, Spain**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-07-09** , it is considered that it complies with:

- The principles of GMP for active substances³ referred to in Article 47 of Directive 2001/83/EC .

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

azaperone(en)

CLOBENZOREX HYDROCHLORIDE(en)

CLOMIFENE CITRATE(en)

chlortalidone(en)

CLOSANTEL SODIUM DIHYDRATE(en)

FURAZIDIN(en)

gabapentin(en)

lamotrigine(en)

MEBHYDROLIN NAPADISILATE(en)

MENATETRENONE(en)

NITROFURAZONE(en)

QUETIAPINE FUMARATE(en)

TIAZOTIC ACID MORPHOLINUM SALT(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance :azaperone

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture of active substance intermediates

3.1.2 Manufacture of crude active substance

3.1.3 Salt formation / Purification steps:

CRYSTALLIZATION AND CENTRIFUGATION

3.5 General Finishing Steps

3.5.1 Physical processing steps:
drying and sieving

3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

Active Substance :CLOBENZOREX HYDROCHLORIDE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture of active substance intermediates

3.1.2 Manufacture of crude active substance

3.1.3 Salt formation / Purification steps:

Salt formation in the last synthesis step, crystallization and centrifugation

3.5 General Finishing Steps

	<p>3.5.1 Physical processing steps: Drying and sieving</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :CLOMIFENE CITRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: Salt formation, crystallization and centrifugation</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: Drying, sieving, milling o micronization</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :chlortalidone	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: Crystallization and centrifugation</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: drying and sieving. Milling or micronization</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Active Substance :CLOSANTEL SODIUM DIHYDRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation, crystallization and centrifugation
3.5	General Finishing Steps
	3.5.1 Physical processing steps: Drying and sieving. Micronisation 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :FURAZIDIN	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Crystallization and centrifugation
3.5	General Finishing Steps
	3.5.1 Physical processing steps: drying and sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :gabapentin	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Crystallization and centrifugation
3.5	General Finishing Steps
	3.5.1 Physical processing steps:

	<p>drying and sieving</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :lamotrigine	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: Crystallization and centrifugation.</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: drying and sieving</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :MEBHYDROLIN NAPADISILATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: Salt formation in the last synthesis step, crystallization and centrifugation</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: Drying and sieving</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</p>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :MENATETRENONE	

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Cristalization and Centrifugation
3.5	General Finishing Steps
	3.5.1 Physical processing steps: DRYING AND SIEVING 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :NITROFUZONE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Cristalization and Centrifugation
3.5	General Finishing Steps
	3.5.1 Physical processing steps: Drying and sieving. Micronisation 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :QUETIAPINE FUMARATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Salt formation, crystallization and centrifugation
3.5	General Finishing Steps
	3.5.1 Physical processing steps: drying and sieving. Milling, Micronization 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging

	material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance :TIAZOTIC ACID MORPHOLINUM SALT	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: salt formation, crystallization and centrifugation
3.5	General Finishing Steps
	3.5.1 Physical processing steps: drying and sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

This certificate is valid up to 09/07/2021.

2019-07-30

Name and signature of the authorised person of the
Competent Authority of Spain

Confidential
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